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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/619,142	07/19/00	KNOWLES	W KNOWLES/HAIR

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HM22/1031

EXAMINER

KIM, V

ART UNIT	PAPER NUMBER
1614	<i>5</i>

DATE MAILED: 10/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/619,142

Applicant(s)

KNOWLES, W. RAY

Examiner

Vickie Y. Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is subject matter in line 1 before the term "for", whether the claim is directed to a composition or a method. It is not clear whether the pencil marked insertion for the term "comp." Is inserted by the applicant or not. It needs to be clarified and the appropriate correction is required. However this examiner proceeds the examination under the assumption, wherein the correct term would be "method".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 8-15, 19-22 are rejected under 35 U.S.C. 102(e/b) as being anticipated by Bradbury et al (US 6,124,362) or Bazzano (US 5,183,817).

The claims 1-4 and 8-11 read on a composition comprising an effective amount of testosterone blocker such as progesterone and/or minoxidil, and a penetration enhancer, optionally a sunscreen.

The claims 12-15 and 19-22 read on a method of preventing or treating alopecia using the same composition.

First, US'362 teaches a method for regulating the growth and loss of hair using a composition comprising an effective and safe amount of minoxidil and progesterone mixture, sunscreen and a penetration enhancer; see column 24, line 33-61 (penetration enhancers); column 25, lines 40-53 (safe and effective amount of active ingredients); column 26, lines 48-67 (sunscreen); column 5, lines 5-15 & column 27, lines 40-50 (a method of regulating hair growth and preventing of hair loss); and claim 8 (minoxidil and progesterone mixture as hair growth agents).

All the elements are taught by the cited reference.

Second, Bazzano (US'817) also teach all the critical elements (minoxidil and progesterone as active ingredient for hair growth, treating alopecia); see abstract and claim 28, especially column 3-4 and 19-20.

Thus the claimed subject matter is not patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1614

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoke (US5,994,319) in view of Orentreich et al (US 5,053,403), .

Hoke (US'319) teach a synergistic compositions for stimulating hair growth(restoring hair) and preventing alopecia (hair loss), are using a composition of minoxidil in combination with an inhibitor of steroid 5-alpha.reductase (antisense oligonucleotides).

Applicant's claims differ because they require progesterone.

It would have been obvious to one of ordinary skill in the art to substitute progesterone to antisense oligonucleotides when Hoke 's reference is modified with Orentreich et al because Orentreich et al teach progesterone is one of preferable 5-alpha reductase inhibitor.

Orentreich et al teach a method for preventing and treating male-pattern baldness, hirsutism, and sebaceous gland hypertrophy, using a composition comprising a 5-alpha reductase inhibitor such as progesterone via blocking testosterone conversion to it's most active metabolite DHT ; see column 1 and column 2.

One would have been motivated to do so, with reasonable expectation of success, because they have same biological pathway(working via same mechanism), especially progesterone is most active inhibitor and is proven for it's efficacy as well as it's safety, wherein possible side effects are well documented since it has been used in the art for long time.

It is noted that a pharmaceutical formulation with penetration enhancer, or adding sunscreen required by the dependent claims, is not considered to be critical because it is common practice which has been utilized by the skilled artisan in the state of the art as cited by many references in the art; see PTO-892. (e.g.; Bradbury et al ,US 6,124,362).

Conclusion

9. All the pending claims are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Monday-Thursday: 7AM-6PM) and Fax number is (703) 308-7924.



Vickie Kim,
Patent examiner
October 24, 2000



William Jarvis
Primary examiner
Art unit 1614